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nutrition&health

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Comment to Interim Final Rule for Health Claim Concerning Plant Sterol Esters and Coronary Heart Disease (CHD) to Extend Health Claim to Dietary Supplements
Docket Nos: OOP-1275 and OOP-1276

Dear Sir or Madam:

This comment is submitted in response to FDA's invitation for comments in support of broadening the categories of foods eligible to bear the plant sterol ester-CHD health claim. In the preamble to its interim final rule, FDA said that it would consider allowing additional foods to bear the claim based on a showing that the use of plant sterol esters in food products other than spreads and dressings for salad is safe and lawful and providing a validated analytical method that permits accurate determination of the amount of plant sterol esters in these foods. 65 Fed. Reg. 54685, 54707-08 (Sept. 8, 2000).

Cognis Corporation requests that FDA broaden the category of foods eligible to bear the plant sterol ester-CHD health claim to include dietary supplements in softgel form that would provide 0.65 g plant sterol esters per serving, twice a day.

OOP-1275
OOP-1276

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Comment

Sterol Esters Consumed in Dietary Supplements are Safe and Lawful

In its rulemaking on the plant sterol ester health claim, the FDA reviewed data demonstrating that the use of plant sterol esters in spreads and dressings for salad up to 1.6 g/serving is safe and lawful and that the level of plant sterol esters necessary to justify a claim is 1.3 g per day. The FDA therefore concluded that the available data demonstrate that the use of plant sterol esters in spreads and dressings for salads containing at least 0.65 g per serving of plant sterol esters eaten twice a day with meals for a daily total intake of at least 1.3 g is safe and lawful. In reaching this conclusion, the FDA stated that it "is not aware of any scientific evidence that vegetable oil sterol esters would be harmful." 65 Fed. Reg. 54688-89; 21 C.F.R. §§ 101.83(c)(2)(G)(1), (H).

Use of a dietary supplement that is formulated and labeled to provide at least 0.65 g per serving of plant sterol esters eaten twice a day with meals for a daily total intake of at least 1.3 g would be equivalent to the recommended consumption of sterols esters in spreads or dressings. This information is adequate to provide reasonable assurance that such a supplement would not present a significant or unreasonable risk of illness or injury under conditions of use recommended or suggested in labeling or under ordinary conditions of use, and that such a supplement will reasonably be expected to be safe. Therefore, such a supplement would be safe and lawful within the meaning of 21 C.F.R. 101.14(b)(3)(ii).

The Relationship Between Plant Sterol Esters in Dietary Supplements and CHD

In promulgating the interim final rule, FDA considered 10 scientific studies evaluating the relationship between plant sterol esters and blood cholesterol levels in humans. In all of these studies, subjects consumed sterol esters delivered in food carriers, and there was no evidence that the nature of the vehicle for delivering plant sterol esters had any significant effect on the cholesterol-lowering effect.

In addition, in reviewing the studies relating to sterol esters, FDA found that the sterol esters tested produced fairly consistent results regardless of the food carrier and apparent differences in processing techniques. The agency concluded that given the variability of amounts and of food carriers in which plant sterols and plant sterol esters were provided in the diets studied, the response of blood cholesterol levels to plant sterols appears to be consistent and substantial (except for plant sterols from sheanut oil and ricebran oil), and supported by significant scientific agreement. 65 Fed. Reg. 54701.

Based on these data and conclusions, there is significant scientific agreement about the effects of plant sterol esters that is not limited to the form of the vehicle, and therefore these conclusions may be extended to dietary supplements that provide 0.65 g plant sterol esters per serving, twice a day.

This conclusion is further supported by the FDA's analysis of plant stanol esters. In that analysis, the agency considered 21 studies evaluating the relationship between plant stanol esters and blood cholesterol levels in humans. It appears that in only one of these studies did the subjects consume the stanol esters in dietary supplement form, and in that study there was no significant reduction of total or LDL cholesterol (FDA accorded little weight to this study because of design issues). 65 Fed. Reg. 54695. Nevertheless, the FDA concluded that the overall conclusion that stanol esters reduce cholesterol applies equally to dietary supplements and conventional foods.

Accordingly, we conclude that the data reviewed by FDA in its rulemaking on this matter demonstrate that, based on the totality of publicly available scientific evidence, there is significant scientific agreement to support a relationship between the consumption of plant sterol esters in dietary supplements and the risk of CHD.

Validated Analytical Method That Permits Accurate Determination of the Amount of Plant Sterol Esters in Dietary Supplements

In the interim final rule, the FDA approved the use of an analytical method entitled "Determination of Stanols and Sterols in Benecol Softgels," which describes a procedure for determination of both plant stanol esters and sterol esters in softgels (gelatin capsules with a liquid center). This analytical method permits accurate determination of the amount of plant sterol esters in dietary supplements, and meets the requirement for a validated analytical method under 21 CFR 101.70(f).

Conclusion

In conclusion, based on the data and information discussed above, Cognis requests that FDA broaden the category of foods eligible to bear the plant sterol ester-CHD health claim to include dietary supplements in softgel form that would provide 0.65 g plant sterol esters per serving, twice a day.

Very truly yours,

James P. Clark

James P. Clark
Technology Director

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